

### **REMARKS**

Claims 42 and 43 are cancelled.

New claim 44 recites a "composition for topical or transdermal administration comprising: (i) caffeine or hydrocortisone; and (ii) at least about 50% by weight Gilsonite oil, wherein the composition is effective achieving  $17.66 \mu\text{g}/\text{cm}^2/\text{hr}$  skin penetration of the caffeine or  $0.1862 \mu\text{g}/\text{cm}^2/\text{hr}$  skin penetration of the hydrocortisone," as supported by, e.g., ¶¶ [0017] - [0019] and Examples 3 and 4.

In view of the following remarks, reconsideration is respectfully requested.

### **Rejections Under 35 U.S.C. § 112**

Claims 41-43 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse these rejections.

Regarding claim 41, the rejection contends that the phrase "consisting of" is new matter because a composition "consisting only of the two elements" of Gilsonite and the bioactive agent (nicotine, caffeine or hydrocortisone) was allegedly not disclosed. On the contrary, the original specification discloses that Gilsonite may be "possibly even the only ingredient besides the bioactive agent." Specification, p. 6, lines 15-16. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 41.

Regarding claims 42 and 43, the rejection thereof is moot following the cancellation of these claims.

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection contends that the term "the

major proportion," (as part of the phrase "the major proportion ingredient") is unclear. Applicants respectfully disagree.

The phrase "the major proportion ingredient" appears in ¶[0017] of the published version of the application. That paragraph discloses compositions for topical and transdermal administration comprising a bioactive agent and Gilsonite oil in various weight percents, along with, preferably, a pharmaceutically acceptable carrier. The adjective "major" commonly means "greater in number, quantity or extent." Therefore, Applicants respectfully submit that one of ordinary skill in the art would understand claim 1 to be directed to formulations wherein Gilsonite oil constitutes greater than 50% of the composition. Accordingly, Applicants respectfully traverse the rejection and request reconsideration and withdrawal thereof.

**Rejection Under 35 U.S.C. § 103(a)**

Claims 1 and 41 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Orlowski, Canadian Patent No. 2,001,688 ("Orlowski") in view Friedman et al., U.S. Patent No. 7,074,392 ("Friedman"). Applicants respectfully traverse the rejection.

Claim 1 recites a composition for topical or transdermal administration consisting essentially of: (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil, and wherein Gilsonite oil is the major proportion ingredient. As established above, "the major proportion ingredient" means that the ingredient is present in a greater weight percent than other ingredients.

Applicants respectfully submit that the references as applied fail to teach or suggest the claimed composition wherein Gilsonite oil is present in a greater weight percent than other ingredients.

Furthermore, as recognized in the rejection, the transitional phrase "consisting essentially of" limits the claims to the specified ingredients and those that do not materially affect the basic and novel characteristics of the claimed invention. In this case, the basic and novel characteristics include ability of Gilsonite oil to enable the bioactive agent to penetrate the skin. See Specification, Examples 1-4.

The cited references fail to recognize the superior and unexpected property of Gilsonite oil to enable the penetration of skin, nor do they teach or suggest any composition having any significant amount of Gilsonite oil. Instead, Orlowski uses Gilsonite (not Gilsonite oil), as a sealant and notes that it is substantially waterproof. Orlowski, p. 6. As already established, the amount of Gilsonite oil in the formulation of Orlowski would constitute only about 0.3% of the formulation. See Response filed June 22, 2009, pp. 7-8. The record fails to support the contention that 0.3% of Gilsonite oil would be sufficient to achieve the basic and novel characteristics of the claimed invention, nor does the rejection supply any reason for one of ordinary skill in the art to increase the amount of Gilsonite oil beyond that which might be found in the composition of Orlowski.

Regarding claim 41, the references as applied fail to teach or suggest the claimed composition, "**consisting of** (i) nicotine, caffeine or hydrocortisone; and (ii) Gilsonite oil" (emphasis added). The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. MPEP 2111.03. The rejection of claim 41 fails to provide any rationale as to why one of ordinary skill in the art would arrive at the claimed composition.

For these reasons, Applicants respectfully traverse the rejections of Claims 1 and 41 and request reconsideration and withdrawal thereof.

Claims 37-40 and 42-43 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Orlowski in view Friedman and further in view of Forrest, U.S. Patent No. 1,573,765 ("Forrest"). Applicants respectfully traverse the rejection.

In this case, the rejection contends that one of ordinary skill in the art would select a Gilsonite oil fraction having a viscosity of about 5 to 1,000 cps at 25°C, and a specific gravity of about 0.8 to 0.95, because Forrest discloses a distillate oil of Gilsonite that has emulsifying properties. However, the record fails to establish any need for an emulsifier in the compositions of Orlowski or Friedman, nor any other reason why one of ordinary skill in the art would combine the references in the manner suggested by the rejection.

Applicants respectfully submit that the obviousness rejection of these claims fails to meet the legally-required standard. Although the Examiner did not expressly identify a specific rationale for the rejection, it appears to be the rationale of "simple substitution of one known element for another to obtain predictable results." MPEP 2143.B.

To reject a claim based on this rationale, Office personnel must resolve the Graham factual inquiries and then articulate the following:

- (1) a finding that the prior art contained a device (method, product, etc.) which differed from the claimed device by the substitution of some components (step, element, etc.) with other components;
- (2) a finding that the substituted components and their functions were known in the art;
- (3) a finding that one of ordinary skill in the art could have substituted one known element for another, and the results of the substitution would have been predictable; and
- (4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. *Id.*

In this case, the rejection fails to satisfy factual inquiries (2) and (3) of the rationale. As noted above, the rejection cites no support for factual inquiry (2), a finding that Gilsonite oil was known in the art to achieve skin penetration. Furthermore, there is no factual support for any finding of (3) that one of ordinary skill in the art could have substituted the Gilsonite oil of Forrest for the solid mineral Gilsonite of Orlowski, and would have predicted success in doing so. As already well-established in this case, raw Gilsonite and Gilsonite oil have distinct chemical compositions with substantially distinct properties. Declaration of Gary David Fisher, filed August 27, 2008, ¶ 4. The rejection fails to supply adequate reasoning as to why one of ordinary skill in the art would select Gilsonite oil as a component of the claimed compositions for topical or transdermal administration.

Without a reasoned, fact-based explanation supported by the evidence of record, an obviousness rejection cannot stand. *Ex Parte Whalen*, Appeal No. 2007-4423, slip op. at 8 (BPAI, July 23, 2008). Applicants respectfully maintain that the obviousness rejection fails to meet the legally-required findings of fact.

For all of the above reasons, Applicants respectfully traverse the obviousness rejections and request reconsideration and withdrawal thereof.

### **Conclusion**

For the foregoing reasons, allowance of the application is respectfully requested. If there are any questions concerning this response, Applicants' undersigned representative can be reached at the number below.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: December 1, 2009

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